Remarks

Claims 1 through 41 remain pending in the application.

The Office Action rejects claims 1 through 4, 6, 11 through 14, 16, 21 through 24, 26, 31 through 34 and 36 under 35 U.S.C § 102 as anticipated by Tartaglia, Polymer File for Wrapping a Stent Structure, U.S. Patent 5,637,113 (Jun. 10. 1997) under the assertion that Tartaglia discloses a stent wrapped with a polymer film capable of carrying and releasing drugs. The Office action states the stent can be implanted in coronary arteries or any other part of the vasculature where mechanical opening force is necessary to keep the vessel open. The Office Action asserts that depending on where the stent is implanted depends on where the therapeutic drug, such as an anti-inflammatory agent, is injected. (The applicant takes this to mean that the examiner is asserting that the site of "injection" depends on where the stent is implanted.) The Examiner also asserts that if the stent is placed near the endocardial or peri-adventitial area, the therapeutic agent will be injected from these areas.

The Office Action ignores the limitations of the Applicant's claims. In claims 1 through 4, 6, 11 through 14, 16, 21 through 24, 26, 31 through 34 and 36, the Applicant's limitations include injecting a therapeutic agent comprising an anti-restenosis agent into the myocardium proximate the coronary blood vessel. Contrary to the Examiner's assertion, Tartaglia fails to disclose injecting a therapeutic agent. Tartaglia does not disclose injecting anything, and Tartaglia does not disclose injecting anything into the myocardium. Tartaglia discloses a

stent wrapped with a drug-impregnated polymer film, or, more succinctly, a drug-eluting stent. Drug-eluting stents are referred to as drug eluting stents because they elute drugs. Elute is a common term in the art of stents, and refers to the slow migration of drugs from the stent. The Oxford English Dictionary defines elute as "to wash (adsorbed matter) away from the substance that has adsorbed it." The Applicant claims injecting a therapeutic agent into the myocardium proximate the coronary blood vessel where the stent is installed as illustrated below. The word "inject" is a common medical term, as well as a common English word, that means "To drive or force (a fluid, etc.) into a passage or cavity, as by means of a syringe, or by some impulsive power; said esp. of the introduction of medicines or other preparations into the cavities or tissues of the body." Oxford English Dictionary. The rejection is based on a confusion between the two terms, and it is a confusion that is inconceivable amongst those of skill in the art, such as cardiologists. It is inconceivable, for example, that a cardiologist would mistakenly elute a bolus of epinephrine into the blood stream of a heart attack patient in light of ACLS guidelines advising him to inject a bolus of epinephrine.

As clearly claimed by the Applicant, the therapeutic agent is injected in the heart wall (myocardium) proximate to the vessel. Tartaglia does not disclose injecting anything into the heart wall proximate to the vessel containing the stent. Tartaglia's stent elutes agents within the coronary vessel itself at the point where the stent is deployed. The difference is drastic, as injection of a stent into the myocardium, if possible, would likely be lethal and would accomplish no known

purpose. Since Tartaglia fails to disclose injection of anything into the myocardium, Tartaglia does not anticipate the Applicant's claimed invention.

The rejection is based on the unfounded assumption that if therapeutic agent is placed near the endocardial area or the peri-adventitial area, it will somehow be "injected" into the myocardium, is wrong. Tartaglia provides no mechanism by which his device might inject therapeutic agent into the myocardium. If the assumption is that some therapeutic agent will migrate from the stent into the myocardium, it is pure speculation. The Examiner offers no evidence that such a migration of eluted compound will occur, and Tartaglia does not suggest that it will. Thus, for this third reason, Tartaglia does not anticipate the claimed inventions.

The Office Action rejects claim 41 as anticipated by Kunz et al., Therapeutic Inhibitor of Vascular Smooth Muscle Cells, U.S. Patent 5,981,568 (Nov. 9, 1999) under the assertion that Kunz discloses a kit comprising a catheter for delivery of a therapeutic agent, at least one dosage of a therapeutic agent, as well as instruction means for their use which is used to inhibit stenosis or restenosis of a blood vessel.

The Office Action ignores the limitations claimed by the Applicant in claim 41. The limitations of claim 41 include a catheter having means for introducing a therapeutic agent into in a perivascular space surrounding the blood vessel and instructions for use of the catheter that include positioning the means for introducing the agent into the perivascular space. Kunz fails to disclose a catheter or instructions relating to positioning into the perivascular space. Contrary to the Office

Action's assertions, Kunz instructions discuss positioning its catheter in a lumen of a mammalian vessel. (Col. 41, ll. 5-10). Kunz agent is released inside the blood vessel. The claim requires positioning the means for introducing in the perivascular space surrounding the blood vessel. There is no discussion in Kunz relating to perivascular positioning. (The Examiner's citation to col. 10, line 63 to col. 11, line 5 is inapposite, and the Applicant is unable to identify any corresponding disclosure in Kunz.) Since Kunz fails to disclose at least one limitation claimed by the Applicant, Kunz does not anticipate the Applicant's claimed. Therefore, withdrawal of this rejection is requested.

The Office Action rejects claims 5, 7, 15, 17, 25, 27, 35 and 37 as obvious over Tartaglia in view of Stevens, et al., Method for Delivery of Therapeutic Agents to the Heart, U.S. Patent 6,152,141 (Nov. 28, 2000) under the assertion that Stevens discloses many agent delivery techniques such as injecting the agent directly into the myocardium by piercing the artery wall. The Office Action further asserts the piercing in Stevens is done distal to the stent site. The Office Action also asserts another agent technique is a stent impregnated with a desired agent for a timed release to the surrounding vasculature and it would have been obvious to one with ordinary skill in the art at the time of the invention to combine Stevens with Tartaglia.

The proposed combination of Stevens and Tartaglia fails to meet the limitations of the Applicant's claimed invention. The limitations of claims 5, 7, 15, 17, 25, 27, 35 and 37 include injecting a therapeutic agent comprising an anti-restenosis agent into the myocardium proximate the coronary blood vessel.

Tartaglia fails to disclose injecting an agent into the myocardium proximate to the coronary blood vessel as previously discussed. Stevens also fails to disclose injecting an anti-restenosis agent proximate the coronary vessel. The Applicant claims include limitations to a anti-restenosis agent while Stevens is directed towards cardioplegic agents. Cardioplegic agents are agents that, upon administration, temporarily arrest cardiac activity. In contrast, anti-restenosis agents prevent the reoccurrence of a constriction or narrowing of a blood vessel. Since the proposed combination of Stevens and Tartaglia fails to meet all the limitations of the Applicant's claimed invention, the combination does not render obvious the Applicant's claimed invention.

Regarding distal injection limitation of claims 5, 7, 25 and 35, the Examiner misunderstands Stevens. Stevens explicitly states the injection is accomplished upstream of the desired region. Upstream is proximal, downstream is distal. The claims are directly contrary to Stevens, and it is clear that as to this limitation Stevens teaches away from the claimed invention.

The Office Action rejects claims 8, 10, 18, 20, 28, 30, 38 and 40 as obvious over Tartaglia as applied to claim 1 in view of Alt, Vascular and Endoluminal Stents with Improved Coatings, U.S. Patent 6,099,561 (Aug. 8, 2000) under the assertion that Alt discloses a gene transfer agent, which can be used to prevent restenosis that can be incorporated in a microsphere or liposome form and it would have been obvious to one with ordinary skill in the art at the time of the invention to combine Alt with Tartaglia as Tartaglia discloses that other therapeutic drugs may be used with the invention.

The proposed combination of Stevens and Alt fails to meet the limitations of the Applicant's claims 8, 10, 18, 20, 28, 30, 38 and 40. The limitations of claims 8, 10, 18, 20, 28, 30, 38 and 40 include injecting a therapeutic agent comprising an anti-restenosis agent into the myocardium proximate the coronary blood vessel. Tartaglia fails to disclose injecting an agent into the myocardium proximate to the coronary blood vessel as discussed previously. Alt also fails to teach or suggest injecting an anti-restenosis agent proximate the coronary vessel. Alt is directed towards stents with coatings such as a gene transfer agent. Alt does not disclose injecting an agent into the myocardium proximate a coronary vessel after stent placement. Since the proposed combination of Stevens and Alt fails to meet all the limitations claimed by the Applicant, the references do not render obvious the Applicant's claimed invention.

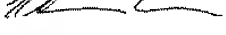
The Office Action rejects claims 9, 19, 29 and 39 obvious over Tartaglia as applied to claim 1 in view of Buscemi, Polymerization Angioplasty Balloon Implant Device, U.S. Patent 5,443,495 (Aug. 22, 1995) under the assertion that Buscemi discloses a highly active cross-linking agents, which prevent stenosis by hardening the stent, that are encapsulated within micelles. The Office Action further asserts it would have been obvious to one of ordinary skill at the time of invention to combine Buscemi with Tartaglia as both inventions are directed to stents and angioplasty procedures.

The Office Action is ignoring the limitations claimed by the Applicant. As previously discussed, Tartaglia fails to teach or suggest injecting an agent into the myocardium proximate to the coronary blood vessel. Buscemi also fails to

teach or suggest injecting an agent into the myocardium proximate to the coronary blood vessel. The Buscemi device comprises a balloon **10** comprising a body portion **14**. (See Figure 1 and 2 and col. 3, lines 61-68 as well as col. 4, ll. 1 -8.) The micelles discussed in Buscemi are disposed within the body portion of the balloon. In contrast to the Applicant's claimed invention, any agent disclosed in Buscemi would be released within the coronary vessel at the sight of the implantation and not into the myocardium proximate to the vessel. Since the proposed combination of Tartaglia and Buscemi does not meet several limitations claimed by the Applicant, the references do not render obvious the Applicant's claims 9, 19, 29 and 39. Withdrawal of the rejection is therefore requested.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: February 12, 2007 By: 

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